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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,949	02/10/2006	Marie-Odile Galcera Contour	427.100	8712

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EXAMINER	
CHENG, KAREN	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,949	GALCERA CONTOUR ET AL.	
	Examiner	Art Unit	
	Karen Cheng	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 1-4,14 and 15 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5-7 and 13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/22/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are currently pending in the instant application.

Lack of Unity Requirement

Claims 1-15 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision set forth in PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 further states unity of invention as referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Special technical features, as defined in PCT Annex B, Part 1(b), include those technical features which define a contribution over the prior art.

PCT Annex B, Part 1(e) provides combinations of different categories of claims and states:

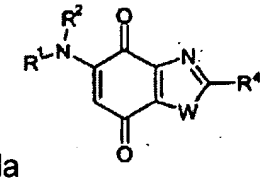
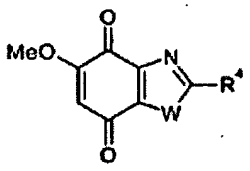
"The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

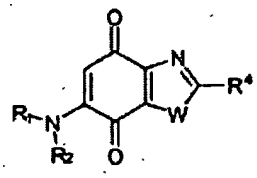
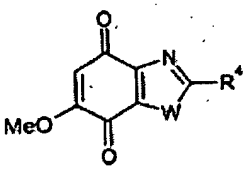
(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

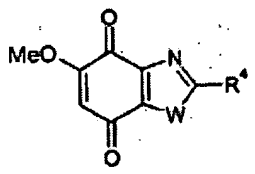
Group I: Claims 1-2 drawn to a process for the preparation of a compound of the following formula  wherein W can be sulfur or oxygen, and the other variables are as defined with said process comprising reaction a compound of the following formula  .

Group II: Claims 3-4 drawn to a process for the preparation of a compound of the following formula  wherein W can be sulfur or oxygen, and the other variables are as defined with said process comprising reaction a compound of the following formula  .

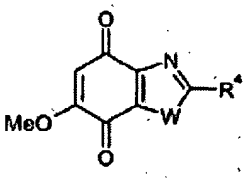
Group III: Claims 5-7 and 13 drawn to compounds and compositions of the compound listed in claim 5.

Group IV: Claim 14 drawn to a method of treating of cancer comprising administering a compound of claim 5.

Group V: Claim 15 drawn to a compound of the following formulas:



and

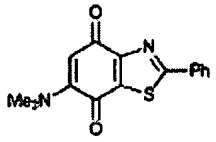
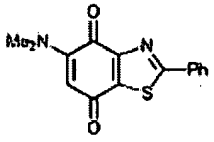


In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again this list is not exhaustive as it would be impossible to write out all groups under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a process of preparation or a method of use) by identifying another specific embodiment of similar scope not listed in the exemplary groups of the invention and examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species or a single disclosed species for a single method of use or preparation and the examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical

features. . .those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Groups I-V lack unity of invention because, pursuant to 37 CFR 1.475(a), there is no structural moiety common to all the Groups as defined. Additionally, Lyon *et al* disclose compounds of  and  (see J. Chem. Soc. Perkin Transactions 1: Organic and Bio-Organic Chemistry, Vol. 4, 1999, p. 437-442) the same structural moiety found in Groups I-IV. Therefore, Claims 1-15 are not so linked as to form a single general inventive concept, and there is lack of unity of invention. The variables vary extensively and, when taken as a whole, result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, ***or*** a method of use.

Furthermore, with respect to **Groups I-V**, even if unity of invention under 36 CFR 1.475(a) is not lacking, a national stage application, under 37 CFR 1.475(b), containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to only one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or
(4) A process and an apparatus or means specially designed for carrying out said process; or
(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specially designed for carrying out said process.

Moreover, according to 37 CFR 1.475(c), if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case, the claims are drawn to multiple products and more than one process of preparation using different products. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

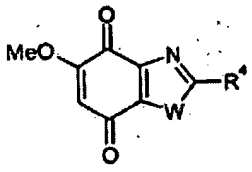
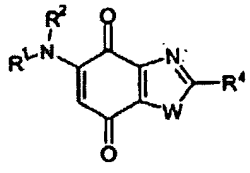
The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Election

During a telephone conversation with Charles Muserlian on March 23, 2007 a provisional election was made with traverse to prosecute the invention of Group III, claims 5-7 and 13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-4 and 14-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

As discussed in the lack of unity requirement, there is no special technical feature that is found in all the Groups. Each Group is drawn to a compound of a different formula – for example, Group V is drawn to a compound of formula  and Group III does not contain the compounds of that formula. Additionally, compounds falling within the formula  have already been disclosed in the prior art (see Lyon *et al*). Thus a lack of unity of invention has been found, and restriction for examination purposes is proper and is maintained.

Priority

The application is a 371 of International Application No. PCT/FR04/01578, filed on 06/24/2004, which claims the benefit of foreign priority under 35 U.S.C. 119, to French Application No. 0307648, filed on 06/25/2003.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed on 12/22/05 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

The nature of the invention is directed to a pharmaceutical composition for the treatment of cancer comprising an effective amount of a compound of claim 5 sufficient to treat cancer and an inert pharmaceutical carrier.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat diseases such as cancer). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that that contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any preventive regimen on its fact.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants' claims include the treatment of any cancer. The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types and that cancer classification has been based primarily on morphological appearance of the tumor. Tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al. page 531). Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them. It is also known in the prior art (Hortobagyi, p. 974) that the several genes, including p53, bcl-2, c-myc, and c-myb, HER-2/neu, and cyclin D, have all been found in abnormal levels in patients with breast cancer. However, the number and types of mutations necessary for development of breast cancer are not known. These examples illustrate the different cellular mechanisms believed to be involved in the progression of cancer, and thus showcase the unpredictability in the art, especially in regards to treatment protocols.

The amount of direction or guidance present and the presence or absence of working examples

The specification describes assays that measure the phosphatase activity of the Cdc25C, the tyrosine phosphatase activity of the CD45 enzyme, and anti-proliferative activity of human prostate and pancreas cancer cells when the claimed compounds are

administered (p. 69-71). However, no indication of the effect of the compound in living organisms (*in vivo)* is given. Additionally there are no tests performed on subjects that show signs of cancer.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include the treatment of cancer, but does not specify who/what is being treated. The specification only provides evidence for the effect the compounds have on enzymes that have been shown to play a roll in cell division. However no test results disclosing the actual effect of the compounds on subjects that show evidence of any disease has been shown. It is known that promising in vitro results do not necessarily translate to successful treatments when administered *in vivo*.

The quantity or experimentation needed and the level of skill in the art

It would require undue experimentation of one of ordinary skill in the art to ascertain the effectiveness of the compound in the treatment and prevention of cancer. Factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. Cancer treatment depends on the different causative agents and cellular mechanisms involved in each type of cancer. Consequently, differ treatment protocols are required, depending on the type of cancer present. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of treating cancer, and the lack of working examples regarding the activity as claimed, one

skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, it is apparent that undue experimentation is necessary because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Therefore, claim 13 is rejected under 35 U.S.C. § 112, 1st paragraph. This rejection can be overcome by deleting "treatment of cancer" from the claim.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5-7 and 13 rejected under 35 U.S.C. 102(a) as being anticipated by Galcera Contour *et al* (see WO Pub No. 2003/055868). Galcera Contour *et al* disclose compounds that are the same as claimed by applicants. See Examples 63, 67-77, 80-88, 104-105, 109-113, 118-120, 126, 129-130. Pharmaceutical compositions and medicaments containing said compounds are disclosed on p. 40.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

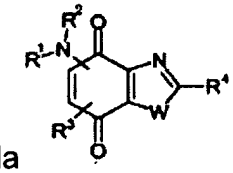
Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 13 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/562625. Although the conflicting claims are not identical, they are not patentably distinct from the pending claims because applicants are claiming compounds, such as 2-(2-chloro-6-fluorophenyl)-5-{[2-(dimethylamino)ethyl]amino}-1,3 benzothiazole-4,7-dione.

Conflicting claims 1-3 of copending Application No. 10/562625 are drawn to compounds of formula  wherein R^1 and R^2 represent alkyl, R^3 represents a hydrogen, R^4 represents a cycloalkyl or carbocyclic aryl radical optionally substituted, and W is O or S. Specifically preferences towards compounds, such as 2-(2-chloro-6-fluorophenyl)-5-{[2-(dimethylamino)ethyl]amino}-1,3 benzothiazole-4,7-dione, are found in claim 3.

The difference between the claims at issue and the conflicting claims is found in the scope of the claims. The instant claims are drawn to a composition comprising the compounds discussed above while the conflicting claims are drawn to products that contain said compounds in combination with at least one other anti-cancer agent for a therapeutic use. However, the composition of the instant claim can contain an anti-cancer agent as found within the conflicting claims.

Therefore, it would have been obvious to one of ordinary skill in the art, when faced with the conflicting claims 1-3 of Application No. 10/562625 to synthesize applicants' instantly claimed composition for use in treatment of cancer, since compounds of similar scope had been administered for the same use. The motivation would be the expectation of success in use of applicants' compounds in use of treating cancer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Objections: Content of Specification

The specification does not incorporate cross reference to related applications. The specification should contain the following sections below, as applicable:

b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

This should include foreign priority to foreign applications.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains the language "said". Correction is required. See MPEP § 608.01(b).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REBECCA ANDERSON
PATENT EXAMINER

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Patent Examiner, AU 1626

Joseph McKane
Supervisory Patent Examiner, AU 1626